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Date: 9/5/2005  
Time: 10:35:33

## Continuity Information for 10/052323

### Parent Data

10052323is a continuation in part of 09563826Which Claims Priority from Provisional Application 60132216Which is a continuation in part of 09533149Which is a continuation in part of 09402527is a national stage entry of PCT/US98/16739 International Filing Date: 08/13/1998Which Claims Priority from Provisional Application 60055520Which Claims Priority from Provisional Application 60075113

### Child Data

10116963 is a continuation in part of 0953314910346021 is a continuation in part of 10116963PCT/US03/01599 is a continuation of 10052323

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## Inventor Information for 10/052323

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 **PALM INTRANET**Day : Monday  
Date: 9/5/2005  
Time: 10:43:25**Application Number Information**Application Number: **10/052323****Assignments**Filing or 371(c) Date: **01/18/2002**Effective Date: **01/18/2002**Application Received: **01/23/2002**Pat. Num./Pub. Num.: **/20030125278**Issue Date: **00/00/0000**Date of Abandonment: **00/00/0000**Attorney Docket Number: **858610-2003.2**Status: **71 /RESPONSE TO NON-FINAL OFFICE ACTION ENTERED  
AND FORWARDED TO EXAMINER**Confirmation Number: **3301**Title of Invention: **IMMUNIZATION OF ANIMALS BY TOPICAL APPLICATIONS OF A  
SALMONELLA-BASED VECTOR**Examiner Number: **77509 /WOITACH, JOSEPH**Group Art Unit: **1632** IFW IMAGEClass/Subclass: **514/044.000**Lost Case: **NO**

Interference Number:

Unmatched Petition: **NO**L&R Code: Secrecy Code:1Third Level Review: **YES** Secrecy Order: **NO**Status Date: **06/28/2005**

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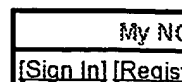
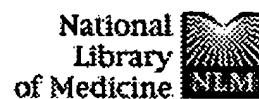
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## OBJECTS AND SUMMARY OF THE INVENTION

[0022] Non-invasive vaccination onto the skin (NIVS) can improve vaccination schemes because skin is an immunocompetent tissue and this non-invasive procedure requires no specially trained personnel. Skin-targeted non-invasive gene delivery can achieve localized transgene expression in the skin and the elicitation of immune responses (Tang et al., 1997) and the mechanism for these responses is different than that from topical application of protein-based vaccines in conjunction with cholera toxin (Glenn et al., 1998). These results indicate that vector-based NIVS is a novel and efficient method for the delivery of vaccines. The simple, effective, economical and painless immunization protocol of the present invention should make vaccination less dependent upon medical resources and, therefore, increase the annual utilization rate of vaccinations.

[0032] Also, the invention provides compositions used in the methods. For instance, the invention provides a prophylactic vaccine or a therapeutic vaccine or an immunological or a therapeutic composition comprising the vector, e.g., for use in inducing or stimulating a response via topical application and/or via mucosal and/or nasal and/or perlingual and/or buccal and/or oral and/or oral cavity administration.



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1: Vaccine. 1997 Jun;15(8):818-20.

[Related Articles, Links](#)**Mucosal immunization with DNA-liposome complexes.**Klavinskis LS, Gao L, Barnfield C, Lehner T, Parker S.

Department of Immunology, Guy's Hospital Medical School, United Medical School of Guy's Hospital, London, UK.

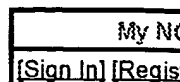
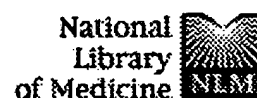
The mucosal surfaces represent the primary site for transmission of several viruses including HIV. To prevent mucosal transmission and dissemination to the regional lymph nodes, an effective HIV vaccine may need to stimulate immune responses at the genital and rectal mucosa. Optimal induction of mucosal immunity in general requires targeting antigens to the specialized antigen presenting cells of mucosal associated lymphoid tissues. The nasal mucosa may provide a simple, non-invasive route to deliver DNA encoding the introduced gene to stimulate mucosal immunity. As a first step to evaluate the feasibility of this approach, we have investigated as a model system, systemic and mucosal immune responses elicited to firefly luciferase generated by DNA immunization. Incorporating DNA into liposomes with cationic lipids enhanced luciferase expression in nasal tissue, and was associated with induction of a humoral response in serum and vaginal fluids and also a proliferative and cytotoxic T lymphocyte response in the spleen and iliac lymph nodes draining the genital and rectal mucosa.

PMID: 9234523 [PubMed - indexed for MEDLINE]

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1: Biochim Biophys Acta. 2002 Aug 15;1572(1):1-9.

Related Articles, Links

**Enhanced delivery of naked DNA to the skin by non-invasive in vivo electroporation.****Zhang L, Nolan E, Kreitschitz S, Rabussay DP.**

Department of Research and Development, Genetronics, Inc., San Diego, CA 92121-1334, USA. lzhang@genetronics.com

DNA delivery to skin may be useful for the treatment of skin diseases, DNA vaccinations, and other gene therapy applications requiring local or systemic distribution of a transgene product. However, the effective, consistent and patient-friendly transfection of skin cells remains a challenge. In a mouse model, we evaluated the effectiveness of intradermal injection of plasmid DNA followed by noninvasive in vivo electroporation (EP) as a method to improve transfection in skin. We achieved a several hundred-fold stimulation of gene expression by EP, sufficient to produce clinically relevant amounts of transgene product. We studied the effect of DNA dose and time after treatment as well as various EP pulse parameters on the efficiency of gene expression. EP under conditions of constant charge transfer revealed that the applied voltage was the main determinant for transgene expression efficiency while other pulse parameters had lesser effects. Patient-friendly, noninvasive meander electrodes which we designed for clinical applications proved equally effective and safe as plate electrodes. We also showed for the first time that noninvasive EP is effective in stimulating transfection and gene expression in human skin, particularly in the epidermis. Our findings demonstrate the applicability of EP-enhanced DNA delivery to skin for gene therapy, DNA immunization and other areas.

PMID: 12204326 [PubMed - indexed for MEDLINE]

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